



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,259	02/14/2006	Michael Schutz	DEBE:046US	3637
32425 7590 10/29/2007 FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701			EXAMINER TSAY, MARSHA M	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 10/29/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,259	SCHUTZ ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1656

This Office action is in response to Applicants' remarks received August 17, 2007.

Claim 6 is canceled. Claim 1-5, 7-18 is pending and currently under examination.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Priority: The priority date is June 24, 2002.

Objections and Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7-12, 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4 recite p12-similar bacteriophage tail protein. The claims are indefinite because there is no clear definition of what a "p12-similar" bacteriophage tail protein is, i.e. what is the degree of similarity, similarity in binding, function, structure, etc. The specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 15 recites the limitation "fluorescence-marked endotoxin" in the claim. There is insufficient antecedent basis for this limitation in the claim and its parent claim.

Art Unit: 1656

Claims 2-3, 5, 7-12, 14, 16-17 are included in this rejection because they are dependent on the above claims and fail to cure the defect.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 11, 15 remain rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al. (1999 Virus Research 60: 95-99; previously cited). For examination purposes, “p-12 similar” has been given its broadest meaning and can encompass any bacteriophage tail protein.

Suzuki et al. teach the specific interaction of fused H protein of bacteriophage ϕ X174 with receptor lipopolysaccharides (LPS). Various concentrations of HisH (histidine-tagged H protein) were adsorbed onto 96 flat-bottom wells, rinsed, and incubated with a sample of biotinylated LPS (p. 97 col. 2; claims 1, 11). The wells were washed to remove unbound LPS, and then added with streptavidin-peroxidase complex (p. 98 col. 1; claims 2). The bound biotinylated LPSs were detected at absorbance of 490 nm (p. 98 Fig. 3; claims 2-3, 15). In Figure 3, Suzuki et al. teach the dose-dependent binding of biotinylated LPS from *E. coli* to HisH (histidine-tagged H protein) (p. 98; claims 1, 3, 11, 15).

In their remarks, Applicants assert as presented for reconsideration, all of the claims recite the presence of bivalent ions in the incubation step. Applicants further assert that Suzuki et al. fail to disclose the presence of bivalent ions in the incubation step. Applicants' arguments have been fully considered but they are not persuasive.

As noted above, the "p-12 similar" language has been given its broadest meaning and can therefore, encompass any bacteriophage protein since neither the instant claims nor the specification provide a clear definition of what is meant by "p-12 similar". Regarding the amendment to claim 4, now reciting the presence of bivalent ions in the incubation step, claims 4, 7, and 10 have been withdrawn from the 35 U.S.C. 102(b) rejection as being anticipated by Suzuki et al.

Claims 1-3, 15 remain rejected under 35 U.S.C. 102(b) as being anticipated by Baxa et al. (1996 Biophysical Journal 71: 2040-2048; previously cited). For examination purposes, "p-12 similar" has been given its broadest meaning and can encompass any bacteriophage tail protein.

Baxa et al. teach bacteriophage p22 tail protein binds to the O-antigen structure in *Salmonella* lipopolysaccharide (LPS) (p. 2040). Soluble tailspikes were studied using octa- and dodecasaccharides comprising two and three O-antigen repeats of *Salmonella* LPSs (p. 2040). Baxa et al. teach LPS fragments were chemically labeled at their reducing ends with fluorophore Amc (p. 2041 col. 2; claim 15). Baxa et al. teach p22 tailspike proteins were incubated with labeled LPS fragments, wherein aliquots of bound bacteriophage tail protein-LPS were removed, and analyzed by reverse-phase HPLC on an ODS column at a flow rate of 1 mL/min. (p. 2042

Art Unit: 1656

col. 1; claims 1-2). The Amc label was detected at an excitation wavelength of 360 nm and an emission wavelength of 450 nm (p. 2042 col. 1; claim 3).

In their remarks, Applicants assert as presented for reconsideration, all of the claims recite the presence of bivalent ions in the incubation step. Applicants further assert that Baxa et al. fail to disclose the presence of bivalent ions in the incubation step. Applicants' arguments have been fully considered but they are not persuasive.

As noted above, the "p-12 similar" language has been given its broadest meaning and can therefore, encompass any bacteriophage protein since neither the instant claims nor the specification provide a clear definition of what is meant by "p-12 similar". Regarding Applicants' argument that all of the claims now recite the presence of bivalent ions in the incubation step, it should be noted that this limitation was added to claim 4, which was not included in the previous 35 U.S.C. 102(b) rejection as being anticipated by Baxa et al.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

Art Unit: 1656

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 13-16, 18 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-28 of copending Application No. 10583415 ('415). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the '415 claims are both drawn to a method for detecting endotoxin comprising the steps of incubating a sample with bacteriophage tail proteins immobilized on a surface, and removing and/or detecting the phage tail protein-endotoxin complex by spectroscopic means.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Art Unit: 1656

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

October 25, 2007

re. Roishi
MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER